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IS 6333 (1985): Propyl p-hydroxybenzoate for Cosmetic Industry [PCD 19: Cosmetics]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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IS : 6333 - 1985

(Reaffirmed 2001)

Indian Standard

SPECIFICATION FOR
PROPYL *p*-HYDROXYBENZOATE FOR
COSMETIC INDUSTRY

(Second Revision)

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

**AMENDMENT NO. 1 JANUARY 1999
TO
IS 6333 : 1985 SPECIFICATION FOR
PROPYL *p*-HYDROXYBENZOATE FOR
COSMETIC INDUSTRY**

(Second Revision)

[Page 4, Table 1, Sl No. (ii), col 3] — Substitute '2' for '1'

[Page 4, Table 1, Sl No. (iii), col 3] — Substitute '10' for '5'.

(PCD 19)

AMENDMENT NO. 2 MAY 2002
TO
IS 6333 : 1985 SPECIFICATION FOR PROPYL
***p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY**
(*Second Revision*)

[*Page 4, Table 1, Sl No. (iii), col 3 (see also Amendment No. 1)*] —
Substitute '20' for '10'.

(*Page 6, clause A-3.2.1, line 1*) — Substitute '1.000 g' for '2.000 g'

(*Pages 7 and 8, clauses A-5 to A-5.2*) — Substitute the following for the
existing:

A-5 ASSAY

A-5.1 Reagents

A-5.1.1 *Standard Sodium Hydroxide Solution* — 1 N.

A-5.1.2 *Standard Sulphuric Acid* — 1 N.

A-5.1.3 *Bromothymol Blue Indicator Solution*

A-5.1.4 *Phosphate Buffer*

A-5.2 Procedure

Transfer to a flask equipped for refluxing under a water-cooled condenser about 2 g of propyl paraben, accurately weighed, add 40.0 ml of 1 N standard sodium hydroxide solution, and rinse the sides of the flask with water. Reflux for 1 hour and cool. Add 5 drops of bromothymol blue indicator solution, and titrate the excess sodium hydroxide with 1 N standard sulphuric acid to a pH of 6.6 by matching the colour of pH 6.6 phosphate buffer containing the same proportion of indicator. Perform a blank determination. Each ml of 1 N sodium hydroxide is equivalent to 180.15 mg of $C_{10}H_{12}O_3$.

(PCD 19)

Indian Standard

SPECIFICATION FOR PROPYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY (*Second Revision*)

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(*Continued on page 2*)

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Indian Standard
SPECIFICATION FOR
PROPYL *p*-HYDROXYBENZOATE FOR
COSMETIC INDUSTRY
(*Second Revision*)

0. FOREWORD

0.1 This Indian Standard (Second Revision) was adopted by the Indian Standards Institution on 11 November 1985, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

0.2 This standard was first published in 1971 and subsequently revised in 1977. Initially while reviewing this standard, the Cosmetics Sectional Committee had agreed to indicate separately the essential and the optional requirements. Subsequently this was found non-implementable for certification and therefore in this revision only a single set of requirement have been stipulated.

0.3 Propyl *p*-hydroxybenzoate is used as preservative in the cosmetic industry; it prevents the growth of micro-organisms.

0.4 In this revision, method of assay has been revised and test for sulphate has been modified to align the test method with that given in the Pharmacopoeia of India 1966 (I.P. 1966). The requirement of pH has been deleted and replaced with a test reaction in line with I.P. 1966. Due to strong reservations regarding the use of potassium cyanide in a cosmetic testing laboratory, in this revision, potassium cyanide method for test of heavy metals has been replaced by hydrogen sulphide method.

0.5 In the preparation of this standard, assistance has been obtained from T.G.A. Specification No. 67 'Propyl *para*-hydroxybenzoate' of the Board of Standards, the Toilet Goods Association Inc., New York, 1971, and from the T.P.F. Specification No. 33 'Propyl *para*-hydroxybenzoate' of the Toilet Preparations Federation Ltd, London.

0.6 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in

accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements and the methods of sampling and test for propyl-*p*-hydroxybenzoate for cosmetic industry.

2. REQUIREMENTS

2.1 **Description** — The material shall be in the form of a white, non-hygroscopic powder. The material is sparingly soluble in water (1 part in 2 000 parts) and freely soluble in ethyl alcohol.

2.2 The material shall also comply with the requirements given in Table 1, when tested according to the methods given in Appendix A. Reference to the relevant clauses of Appendix A is given in col 4 of Table 1.

TABLE 1 REQUIREMENTS FOR PROPYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

SL No.	CHARACTERISTIC	REQUIREMENT	METHOD OF TEST (REF TO CL No. IN APPENDIX A)
(1)	(2)	(3)	(4)
i)	Melting point, °C	95 to 98	A-2
ii)	Arsenic (as As_2O_3), ppm, <i>Max</i>	1	A-3
iii)	Heavy metals (as Pb), ppm, <i>Max</i>	5	A-4
iv)	Assay, <i>Min</i>	99	A-5
v)	Sulphated ash, percent by mass, <i>Max</i>	0.1	A-6
vi)	Chlorides	To pass test	A-7
vii)	Sulphates	To pass test	A-8
viii)	Reaction	To pass test	A-9

3. PACKING AND MARKING

3.1 **Packing** — The commonly used size and material of construction of containers is 5 kg gusseted polythene bag which is further packed in 5-ply corrugated box of grammage 5 × 110 gsm or the packing shall be subject to agreement between the purchaser and the supplier.

*Rules for rounding off numerical values (*revised*).

3.2 Marking — The containers shall be securely closed and marked with the name and mass of the material in the container, manufacturer's name and trade-mark, if any; batch number in code or otherwise; and the year of manufacture.

3.2.1 The product may also be marked with Standard mark.

3.2.2 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

4. SAMPLING

4.1 The method for preparing representative test samples of the material and the criteria for conformity shall be as prescribed in Appendix B.

A P P E N D I X A

(*Clause 2.2*)

METHODS OF TEST FOR PROPYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

A-1. QUALITY OF REAGENTS

A-1.1 Unless or specified otherwise, pure chemicals and distilled water (*see IS : 1070-1977**) shall be used in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

A-2. DETERMINATION OF MELTING POINT

A-2.1 Apparatus

A-2.1.1 Oil Bath — consisting of liquid paraffin in a glass container.

A-2.1.2 Heat Source — electrical or open flame, capable of being controlled to a desired rate of heating.

A-2.1.3 Capillary Tubes — of glass, 10 cm long and 0.3 to 1.2 mm in internal diameter.

*Specification for water for general laboratory use (*second revision*).

IS : 6333 - 1985

accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

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2.2 The material shall also comply with the requirements given in Table 1, when tested according to the methods given in Appendix A. Reference to the relevant clauses of Appendix A is given in col 4 of Table 1.

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FOR COSMETIC INDUSTRY**

Sl. No.	CHARACTERISTIC	REQUIREMENT	METHOD OF TEST (REF TO CL NO. IN APPENDIX A)
(1)	(2)	(3)	(4)
i)	Melting point, °C	95 to 98	A-2
ii)	Arsenic (as As_2O_3), ppm, <i>Max</i>	1	A-3
iii)	Heavy metals (as Pb), ppm, <i>Max</i>	5	A-4
iv)	Assay, <i>Min</i>	99	A-5
v)	Sulphated ash, percent by mass, <i>Max</i>	0.1	A-6
vi)	Chlorides	To pass test	A-7
vii)	Sulphates	To pass test	A-8
viii)	Reaction	To pass test	A-9

3. PACKING AND MARKING

3.1 **Packing** — The commonly used size and material of construction of containers is 5 kg gusseted polythene bag which is further packed in 5-ply corrugated box of grammage 5 × 110 gsm or the packing shall be subject to agreement between the purchaser and the supplier.

*Rules for rounding off numerical values (*revised*).

3.2 Marking — The containers shall be securely closed and marked with the name and mass of the material in the container, manufacturer's name and trade-mark, if any; batch number in code or otherwise; and the year of manufacture.

3.2.1 The product may also be marked with Standard mark.

3.2.2 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

4. SAMPLING

4.1 The method for preparing representative test samples of the material and the criteria for conformity shall be as prescribed in Appendix B.

A P P E N D I X A

(Clause 2.2)

METHODS OF TEST FOR PROPYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

A-1. QUALITY OF REAGENTS

A-1.1 Unless or specified otherwise, pure chemicals and distilled water (see IS : 1070-1977*) shall be used in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

A-2. DETERMINATION OF MELTING POINT

A-2.1 Apparatus

A-2.1.1 Oil Bath — consisting of liquid paraffin in a glass container.

A-2.1.2 Heat Source — electrical or open flame, capable of being controlled to a desired rate of heating.

A-2.1.3 Capillary Tubes — of glass, 10 cm long and 0.3 to 1.2 mm in internal diameter.

*Specification for water for general laboratory use (second revision).

A-2.1.4 Thermometer — calibrated against a certified thermometer.

A-2.2 Procedure

A-2.2.1 Reduce the sample to a fine powder. Fill in a capillary tube, which is sealed at one end, sufficient quantity of dry powder to form a column 2.5 to 3.5 mm in height when packed down as closely as possible.

A-2.2.2 Heat the bath until a temperature approximately 30°C below the expected melting point is reached. Attach capillary tube containing the powdered sample to the thermometer by wetting both with a drop of liquid paraffin and adjust its height so that the material in the capillary is in level with the thermometer bulb. Return the thermometer to the bath and continue heating with constant stirring at a rate of approximately 3 deg/min until a temperature 3°C below the expected melting point is attained. Then carefully regulate the rate to about 1 to 2 deg/min until the sample is completely melted.

A-2.2.3 The temperature at which the column sample is observed to collapse definitely against the side of the tube at any point shall be taken as the beginning of the melting and the temperature at which the sample becomes liquid throughout shall be taken as the end of melting.

A-2.2.4 Both the temperatures noted shall fall within the specified melting range.

A-3. TEST FOR ARSENIC

A-3.1 Reagents

A-3.1.1 Concentrated Sulphuric Acid — (see IS : 266-1977*).†

A-3.1.2 Concentrated — (see IS : 264-1976†).

A-3.2 Procedure

A-3.2.1 Preparation of Sample — Weigh 2.000 g of the sample in a Kjeldahl flask of 500-ml capacity. Add 5 to 10 ml of concentrated nitric acid followed by 2 ml of concentrated sulphuric acid. Heat cautiously. Add drop by drop more nitric acid, if required, from a pipette to speed up the oxidation of the sample. The total amount of nitric acid shall be noted for use in the control test. When oxidation is complete, the solution is clear and faint yellow; at that stage, add 20 ml of water and again boil to fuming. Ensure removal of all nitric acid.

A-3.2.2 Carry out the test for arsenic with the solution prepared in **A-3.2.1** as given in IS : 2088-1983‡. Compare the stain obtained with that produced with 0.002 mg of arsenic trioxide.

*Specification for sulphuric acid (second revision).

†Specification for nitric acid (second revision).

‡Methods for determination of arsenic (second revision).

A-4. TEST FOR HEAVY METALS

A-4.0 Outline of the Method — The colour produced with hydrogen sulphide solution is matched against that obtained with standard lead solution.

A-4.1 Apparatus

A-4.1.1 Nessler Cylinders — 50 ml capacity.

A-4.2 Reagents

A-4.2.1 Concentrated Hydrochloric Acid — (see IS : 265-1976*).

A-4.2.2 Concentrated Nitric Acid — (see IS : 264-1976†).

A-4.2.3 Dilute Acetic Acid — 6 percent acetic acid. (60 ml diluted to 1 000 ml with water.)

A-4.2.4 Hydrogen Sulphide Solution — saturated

A-4.2.5 Standard Lead Solution — Dissolve 1·600 g of lead nitrate in water and make up the solution to 1 000 ml. Pipette out 10 ml of the solution and dilute again to 1 000 ml with water. One millilitre of this solution contains 0·01 mg of lead (as Pb).

A-4.3 Procedure — Ignite 1·000 g of the material in a silica dish until completely ashed. To the residue add 1 ml of hydrochloric acid and 0·5 ml nitric acid and evaporate to dryness on the steam bath. Dissolve the residue in 5 ml hot water and 1 ml dilute acetic acid and transfer to Nessler cylinder washing in with water. In the second Nessler cylinder, place 1 ml of dilute acetic acid and 2 ml of standard lead solution. Add to each cylinder 10 ml of hydrogen sulphide solution and make up the volume with water to 50 ml. Mix, allow to stand for 10 minutes and then compare the colour produced in the two Nessler cylinders.

A-4.3.1 The limit prescribed in Table 1 shall be taken as not having been exceeded if the intensity of colour produced in the test with the material is not greater than that produced in the second Nessler cylinder.

A-5. ASSAY

A-5.1 Reagents

A-5.1.1 Standard Sodium Thiosulphate Solution — 0·1 N.

A-5.1.2 Standard Bromine Solution — 0·1 N.

A-5.1.3 Sodium Hydroxide Solution — 1 N.

A-5.1.4 Concentrated Hydrochloric Acid — see IS : 265-1976*.

*Specification for hydrochloric acid (second revision).

†Specification for nitric acid (second revision).

A-5.1.5 Potassium Iodide Solution — 50 percent solution (*m/v*).

A-5.1.6 Starch Solution — freshly prepared.

A-5.2 Procedure — Weigh accurately about 0.1 g of the sample in a 250 ml beaker, boil for 30 minutes with 50 ml of 1 N sodium hydroxide solution, replacing the water lost by evaporation. Cool, transfer to a glass-stoppered flask and add immediately 50 ml of 0.1 N bromine and 10 ml of hydrochloric acid. Shake repeatedly during fifteen minutes, allow to stand for fifteen minutes, add 30 ml of solution of potassium iodide and titrate the liberated iodine with 0.1 N sodium thiosulphate solution using solution of starch as indicator. Repeat the experiment with the same quantity of the same reagent in similar manner omitting propyl-*p*-hydroxybenzoate sample. The difference between the titration represents the amount of bromine required by the propyl *p*-hydroxybenzoate sample

Each one ml of 0.1 N bromine is equivalent to .003 005 g of $C_{10}H_{12}O_3$.

A-6. DETERMINATION OF SULPHATED ASH

A-6.1 Reagent

A-6.1.1 Dilute Sulphuric Acid — approximately 4 N.

A-6.2 Procedure — Weigh accurately 1 to 2 g of the sample in a tared crucible. Ignite until thoroughly charred, cool and moisten with 1 ml of dilute sulphuric acid and cautiously ignite until the carbon is completely consumed. Conduct the ignition at a place protected from air currents and use as low a temperature as possible to effect the combustion of carbon. When carbon has completely disappeared, cool the crucible in a desiccator and weigh.

A-6.3 Calculation

$$\text{Sulphated ash, percent by mass} = \frac{100 \times m}{M}$$

where

m = mass in g of the residue obtained, and

M = mass in g of the sample taken for the test.

A-7. TEST FOR CHLORIDES

A-7.1 Apparatus

A-7.1.1 Nessler Cylinders — 50 ml capacity.

A-7.2 Reagents

A-7.2.1 Silver Nitrate Solution — 2 percent.

A-7.2.2 Dilute Nitric Acid — 4 N.

A-7.2.3 Standard Hydrochloric Acid — exactly 0.01 N.

A-7.3 Procedure — Heat 2.000 g of the sample with 100 ml of water, cool, add water to restore to the original volume, and filter through cotton. Use the filtrate for test for chlorides and sulphates (**A-8**). Take 50 ml of the filtrate in a Nessler cylinder and add 1 ml of dilute nitric acid and 1 ml of silver nitrate solution. Carry out a control test in another Nessler cylinder using 1.0 ml of standard hydrochloric acid and the same quantities of other reagents as used with the sample. Allow the cylinders to stand for 5 minutes protected from direct sunlight and compare the turbidity.

A-7.3.1 The sample shall be taken to have passed the test if the turbidity produced with the sample is not greater than that produced in the control test.

A-8. TEST FOR SULPHATES

A-8.1 Reagents

A-8.1.1 Dilute Hydrochloric Acid — 4 N.

A-8.1.2 Barium Chloride Solution — 10 percent.

A-8.2 Procedure — Take a 10 ml aliquot of the filtrate preserved in **A-7.3** in a Nessler cylinder, add a few drops of dilute hydrochloric acid and a few drops of barium chloride solution. Mix and allow to stand for 10 minutes.

A-8.2.1 The sample shall be taken to have passed the test if no turbidity is produced within ten minutes.

A-9. REACTION

A-9.1 Procedure — Heat 0.5 g of sample in 10 ml of water to 80°C, cool and filter. The sample shall be taken to have passed the test, if the filtrate is neutral or slightly acidic to solution of litmus.

A P P E N D I X B

(Clause 4.1)

SAMPLING OF PROPYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

B-1. GENERAL REQUIREMENTS OF SAMPLING

B-1.0 In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observed.

B-1.1 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-1.2 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

B-1.3 The samples shall be placed in clean, dry, air-tight glass or other suitable containers.

B-1.4 Each sample container shall be sealed air-tight with a suitable stopper after filling, and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

B-2. SCALE OF SAMPLING

B-2.1 Lot — All the containers in a single consignment of the material drawn from the same batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

B-2.1.1 Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of this specification.

B-2.2 The number of containers (n) to be chosen from the lot shall depend on the size of the lot (N) and shall be as given below:

<i>Lot Size</i>	<i>No. of Containers to be Selected</i>
(N)	(n)
Up to 50	3
51 „ 150	4
151 „ 300	5
301 „ 500	7
501 and above	10

B-2.3 The containers to be selected for sampling shall be chosen at random from the lot and for this purpose, random number tables shall be used (see IS : 4905-1968*). In case such tables are not available, the following procedure may be adopted:

Starting from any container, count them as 1, 2, 3,..... up to r and so on in a systematic manner, where r is the integral part of N/n (see B-2.2). Every r th container thus counted shall be withdrawn from the lot.

*Methods for random sampling.

B-3. TEST SAMPLES AND REFEREE SAMPLE

B-3.1 Preparation of Test Samples

B-3.1.1 Draw with an appropriate sampling instrument a small portion of the material from different parts of each container selected (*see* **B-2.2**). The total quantity of the material drawn from each container shall be sufficient to conduct the tests for all the characteristic given under 2 and shall be not less than 250 g.

B-3.1.2 Thoroughly mix all portions of the material drawn from the same container. Out of these portions, equal quantity shall be taken from each selected container and shall be well mixed up together so as to form a composite sample weighing not less than 0.5 kg. This composite sample shall be divided into three, equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.1.3 The remaining portion of the material from each container (after the quantity for the formation of composite sample has been taken) shall be divided into three equal parts, each part weighing not less than 100 g. These parts shall be immediately transferred to thoroughly dried bottles which shall then be sealed air-tight with stoppers and labelled with all the particulars of sampling. The material in each such sealed bottle shall constitute an individual test sample. These individual samples shall be separated into three identical sets of samples in such a way that such set has an individual test sample representing each container selected. One of these three sets shall be sent to the purchaser, another to the supplier and the third shall be used for the referee.

B-3.2 Referee Sample — The referee sample shall consist of a composite sample B (**B-3.1.2**) and a set of individual samples (**B-3.1.3**) marked for this purpose and shall bear the seals of the purchaser and the supplier. These shall be kept at a place agreed to between the purchaser and the supplier and shall be used in case of dispute between the two.

B-4. NUMBER OF TESTS

B-4.1 Test for assay shall be conducted on each of the individual samples.

B-4.2 Tests for the remaining characteristics given in Table 1 shall be conducted on the composite sample (**B-3.1.2**).

B-5. CRITERIA FOR CONFORMITY

B-5.1 For Individual Sample — The mean \bar{x} and range R for the test results shall be calculated (range being the difference between the maximum and the minimum test results).

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B-5.1.1 The lot shall be declared to have satisfied the requirement for assay if the value of the expression $(x - 0.6 R)$ is equal to or greater than 99.

B-5.2 For Composite Samples — The test results on the composite sample shall meet the corresponding requirements specified in Table 1.

B-5.3 A lot shall be declared as conforming to this specification if it satisfies the requirements for each of the characteristics listed in Table 1. If the requirements for any of the characteristics are not met, the lot shall be declared to have not satisfied the requirements of the specification.

(Continued from page 2)

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